

REMARKS

Claims 1-10 and 59-74 are pending in the application. Although the Office Action Summary states that claims 1-58 are pending, the Office Action itself confirms that claims 1-10 and 59-74 are pending.¹

Claims 1 and 74 have been amended to delete the language “and mixtures thereof” to improve the clarity and readability of the claims, and to better recite that which Applicant regards as this aspect of his invention. It should be noted, however, that the amendment of these claims to delete this language merely addresses these informalities and in no way concerns the patentability of the invention. From a reading of the claim as a whole, before and after amendment, and particularly in view of the open-ended transition phrase “comprising,” it is clear that the compositions according to these aspects of the invention may comprise mixtures of the recited compositions, including mixtures of the recited skeletal structures of the parent androgens. Thus, no narrowing of the claim scope has occurred and no estoppel arises.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 59-73 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action at page 2 alleges that the alkylcarbonate esters in claims 59-73 are not disclosed in the specification.

¹ It appears that the Office Action Summary attached to the outstanding Office Action is actually the Office Action Summary for the first Office Action mailed on September 18, 2002.

Applicant respectfully traverses this rejection. Claims 59-73, including the specific promoieties recited in each of these claims, are fully disclosed and supported in the specification, for example, at Paragraphs 0038, 0047, 0053 and 0059. One of ordinary skill in the art, having read these claims in view of the specification, would be enabled to make and use the invention as set forth in these claims without undue experimentation. Accordingly, Applicant respectfully submits that the rejection was misplaced, and requests its withdrawal.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-10 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant respectfully disagrees with the assertion in the Office Action that claim 1 as written is confusing. Claim 1 recites, for example and *inter alia*, a composition that comprises a substrate having a skeletal structure of a parent androgen, wherein the substrate comprises a carbon-carbon double bond at the 4 position, and wherein the skeletal structure of the parent androgen comprises androst-4-ene-3 α ,17 β -diol or androst-4-ene-3 β ,17 β -diol, and a promoiety appended to the 17 β -hydroxy oxygen of the substrate as a substitute for the hydroxy hydrogen of the parent androgen, wherein the promoiety comprises an alkylcarbonate ester. This therefore includes androstene-4-ene-3-alpha,17-beta-diol, 17-beta alkylcarbonates, but is not necessarily limited to them. As specifically recited in claim 1, for example, 3-beta,17-beta diols also are within its scope. Claim 1 is

definite within the meaning of Section 112, second paragraph, and thus Applicant believes the rejection on this basis is misplaced.

Although Applicant respectfully traverses the rejection of claims 1-10 regarding use of the well-recognized term “comprises,” Applicant has amended the pending claims to recite a “composition.” This amendment has been made to make explicitly clear that the invention is to be construed broadly to include “compounds,” even if that term is given a narrow interpretation, but also compositions of matter for increasing the concentration of a parent androgen in a subject *in vivo*.

It appears from the Office Action that the examiner may be interpreting the term “compound” necessarily to be a closed term, essentially as if Applicant had used the limiting transition phrase “consisting of.” That meaning was not intended, nor is there any basis for such a limited construction. It is entirely possible for a compound to include components other than those expressly recited in a claim to be present when the claim language uses the open transition phrase “comprising,” as is well established in the law and as has been done here. The unduly narrow construction suggested in the Office Action, carried into the infringement context, would yield the inequitable and, Applicant believes, unlawful result that the mere addition of a trace component not expressly recited in the claim would defeat literal infringement. The open-ended transition phrase used in claim 1 is and was entirely proper. By amending the claims to recite a “composition” rather than a compound, this is made clear. No narrowing of the claim scope results, and no estoppel arises.

Applicant respectfully traverses the rejection of claim 7 on similar grounds. The claim modifies claim 1 by further reciting a carrier. The term is known in the

art, and is a completely legitimate modification of the composition recited in claim 1, as originally presented or as amended here.

In view of the foregoing, Applicant submits that the rejection of claims 1-10 on Section 112, second paragraph grounds was misplaced and should be withdrawn.

Claim Rejections Under 35 U.S.C. §102

MTE Nutrition's A-100

Claims 1-10 have been rejected under 35 U.S.C. § 102(b) (hereinafter "102(b)") as being anticipated by the product A-100 by MTE Nutrition. A printout of a page from MTE Nutrition's Web site regarding the product A-100 was included with the Office Action.

Under 102(b), an applicant is barred from obtaining a patent if the invention was in public use or on sale in the U.S. more than one year prior to the filing date of the application. MTE Nutrition's Web page regarding A-100 contains no information as to when the product was first sold in the U.S. It merely states that the company has been in business since 1997. Therefore, based on the Web page, A-100 cannot be said to have been in use or on sale in this country more than one year prior to the filing of this application.

In addition, the MTE Nutrition Web page regarding A-100 cannot be relied upon as prior art as a printed publication. As stated in section 2128 of the Manual of Patent Examining Procedure, "prior art disclosures on the Internet or on an on-line database are considered to be publicly available as of the date the item was publicly posted. If the publication does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. § 102(a) or

(b)” Because the Web page does not contain a publication date or retrieval date, it cannot be the basis of a rejection under 102(b).

Taizhou Xingye Chemical Co. Ltd

Claims 1-10 also have been rejected under 102(b) as being anticipated by the products 4-androstenediol Methyl Carbonate and 4-androstenediol Ethyl Carbonate manufactured by Taizhou Xingye Chemical Co. Ltd (“Xingye”). The Office Action included printouts of Chem Net and Xingye’s Web pages regarding these products. Again, these Web pages do not include publication or retrieval dates. Also, there are no dates as to when these products were first used or sold in the U.S. Therefore, as similarly stated above, these products manufactured by Xingye cannot be relied upon in a 102(b) rejection.

Twinlab’s Andro Nitrate3 Fuel

Claims 1-10 also have been rejected under 102(b) as being anticipated by Twinlab’s Andro Nitrate3 Fuel. A page from Fitness Connection Nutrition’s Web site selling this product was included with the Office Action. Once again, there are no dates of when the product was first used or sold in the U.S., nor is there a publication or retrieval date. Therefore, the product or the Web page cannot be relied upon as prior art under 102(b).

San A-100 Anabolic Amplifier

Claims 1-10 have been rejected under 102(b) as being anticipated by San A-100 Anabolic Amplifier.² The Web page cited by the Office Action in regards to this

² The Office Action actually states that A-100 is made by Biotest Mag 10. See Office Action, at page 4. Because Biotest does not make A-100, in addition to the

product does not include any dates related to when the product was first used or sold, when the Web page was first published, or when the Web page was retrieved. Therefore, SAN A-100 Anabolic Amplifier cannot be the basis of a 102(b) rejection.

Biotest's Mag 10

Claims 1-10 also have been rejected under 102(b) as being anticipated by Biotest's Mag 10. The manufacturer of Mag 10, Biotest Laboratories, LLC, is the assignee of the invention disclosed in this application. As inventor of the compound in Mag 10, Applicant submits that this product was not used or sold more than one year prior to this application's filing date. The Web page relied on to make the 102(b) rejection does not contradict this fact.

Conclusion

In view of the foregoing, claims 1-10 and 59-74 are in condition for allowance. Applicant requests reconsideration of the application in view hereof.

A check for \$210 is enclosed to cover the extension fee. If this is deficient or if there are any other fees due in connection with the prosecution of this application, please charge the fees to our Deposit Account No. 501324.

Dated: November 4, 2003

Respectfully submitted,



Sarah L. Malcolm
Reg. No. 53,259

fact that SAN A-100 Anabolic Amplifier was cited as a reference, Applicant believes that this rejection was intended to be two separate 102(b) rejections – one based on SAN A-100 Anabolic Amplifier, the other based on Biotest's Mag 10. Accordingly, Applicant has responded to each of these rejections.

CERTIFICATE OF EXPRESS MAILING

Express Mail Label No. EV 260562255 US

Date of Deposit: November 4 , 2003

I hereby certify that this Amendment and Response to Office Action No. 2 is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

